



# FDA Facts:

## Food Safety Enforcement

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**F**or more than 100 years, the U.S. Food and Drug Administration has protected the health of Americans by helping to ensure the safety of the foods the agency regulates.

Protecting America's food supply involves two of the FDA's five strategic priorities.

1. Strengthen the Safety and Integrity of the Global Supply Chain
2. Strengthen Compliance and Enforcement Activities to Support Public Health

### Key Points

- The U.S. food supply is one of the safest in the world.
- The FDA enforces laws passed by Congress and uses its regulatory authority to protect consumers from unsafe foods.
- The agency has a number of options, ranging from warning letters to criminal prosecution. Its choice depends on the risk to public health and the actions taken by the regulated entity.

### Overview

Here are some of the tools used by the FDA to help keep food safe and an explanation of how and when they are used.

### Warning Letters

- **What is it?** A warning letter from the FDA puts individuals or firms on notice that the agency has documented violations of the Federal Food, Drug and Cosmetic Act (FD&C Act) during its inspections or investigations.
- **When is it used?** Warning letters are issued only for violations that could lead to enforcement actions if not corrected.
- **What is the impact?** The use of warning letters is based on the expectation that most individuals and firms will voluntarily comply with the law.
- **What happens next?** The FDA requests that recipients of a warning letter respond to the agency in writing addressing the violations described in the letter. If the violations are

not corrected, the strategies available to the FDA include sequential or concurrent enforcement actions that include recall, injunction, seizure, administrative detention, suspension of registration, and criminal or civil prosecution.

### Recall

- **When is it used?** Recalls are often done voluntarily. The 2011 FDA Food Safety Modernization Act authorizes the FDA to order a recall under certain circumstances when a company fails to voluntarily recall an article of food after being provided with an opportunity to do so.
- **What is the impact?** A recall could potentially remove products that may be harmful from the market.

### Restraining Order or Injunction

- **What is it?** An injunction is a civil judicial process initiated to stop or prevent a violation of the law, such as to halt the flow of violative products in interstate commerce, and to correct the conditions that caused the violation to occur. The FDA can ask a court for a temporary restraining order, a preliminary injunction, or a permanent injunction, depending on the specific violations at issue.
- **When is it used?** Factors considered include the whether there is a hazard requiring immediate action and a seizure is impractical, the continuing threat to public health, and the severity of the violation. Temporary restraining orders are generally sought when the threat is considered immediate.
- **What is the impact?** A temporary restraining order is immediately effective and typically lasts for 10 days. A preliminary injunction, which sometimes, but not always, follows a temporary restraining order, requires a hearing on the evidence of potential harm, and could last for any length of time. A permanent injunction, which sometimes, but not always, follows a preliminary injunction, can be entered following a hearing or as the result of a negotiated settlement, and remains in effect until it is terminated by the court.
- **What happens next?** When an injunction is granted, the FDA has a continuing duty to monitor the injunction and to advise



the court if the defendants fail to obey its terms; if its terms are violated, the FDA will consider additional regulatory action.

## Seizure

- **What is it?** A federal district court action whereby a warrant is issued by the court directing U.S. marshals to take possession of foods considered in violation of the FD&C Act for safety or other reasons.
- **When is it used?** To seize batches or lots of a particular product, or all FDA-regulated products at a facility that violate the law.
- **What is the impact?** If successful, the seized products are either destroyed so that they never enter the marketplace or are reconditioned so that they are brought into compliance with the law.
- **What happens next?** The owner of the seized articles has three options: do nothing and the court will enter a default order, and the seized articles will be destroyed; enter into a Consent Decree with the FDA and agree to pay costs and destroy the food or correct the violation; or contest the action in court.

## Administrative Detention

- **What is it?** An interim final rule issued in May 2011 under the FDA Food Safety Modernization Act that amended the criteria under which the FDA can keep suspect articles of food out of the marketplace for up to 30 days.
- **When is it used?** When the FDA has reason to believe the articles of food are adulterated (e.g., contain impure or unsafe ingredients) or misbranded (e.g., bear false or misleading information in their labeling).
- **What is the impact?** The detained articles of food are not sold or distributed during the detention period.
- **What happens next?** The FDA considers whether an enforcement action, such as a seizure or other form of prosecution, is needed to address violation of the FD&C Act.

## Suspension of Registration

- **What is it?** The 2011 food safety law gives the FDA the authority to prevent the distribution of unsafe food in the United States by suspending the registration of food facilities.
- **When is it used?** The FDA may suspend the registration of a food facility if the agency determines that a food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals and certain other criteria are met.

- **What is the impact?** If a food facility's registration has been suspended, food from that facility cannot be distributed, sold, or otherwise introduced into the United States.
- **What happens next?** Before the suspension is lifted, the FDA can require a food facility with a suspended registration to submit a corrective action plan that demonstrates how the facility plans to correct the actions found by the FDA.

## Prosecution

- **What is it?** Criminal prosecution by the Department of Justice for violations of the FD&C Act. This includes misdemeanor and felony prosecutions.
- **When is it used?** The type of legal action depends on a number of factors, including the severity and scope of the public health threat, and whether the violations are part of a pattern of illegal behavior.
- **What is the impact?** Misdemeanor prosecution under the FD&C Act can have a strong deterrent effect. Once convicted of a misdemeanor, any subsequent violation of the FD&C Act is a felony.
- **What happens next?** Defendants face fines and possible imprisonment.

## For More Information

Resources at [www.fda.gov/Food](http://www.fda.gov/Food) include:

- the latest news on foods that have been withdrawn from the market or seized;
- information about dietary supplements, food labeling and nutrition, and biotechnology; and
- product specific information about many foods and beverages.

## How to Learn About Product Recalls

The FDA has created a Web-based recall search engine that makes it easier and quicker to learn about product recalls. Recall information is presented in an easy-to-read table organized by date, product brand name, product description, reason for recall, recall press release, the recalling firm and, where possible, a photo of the product.

The recalls table can be found at [www.fda.gov/recalls](http://www.fda.gov/recalls).

Mobile recall applications can be downloaded at [www.recalls.gov/food.html](http://www.recalls.gov/food.html).

Created: May 2012